

SEP 6 2002

K011531



CORPORATE HEADQUARTERS

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Dalene T. Binkley
Telephone: (219) 267-1612
Fax: (219) 372-1683

Proprietary Name: Calcium Phosphate Granular Bone Void Filler

Common Name: Calcium phosphate

Classification Name: Bone Void Filler

Device Description: The Calcium Phosphate Granules are biocompatible, resorbable, osteoconductive material for filling bone defects. The granules are designed to be gently packed into bone voids and defects at the time of surgery. The granules provide a scaffold for new bone formation within the defect. Over time, the material is resorbed by osteoclasts and replaced by bone.

Intended Use: Calcium Phosphate Granular Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The granules are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Basis of Substantial Equivalence:

In terms of overall design and intended use, the Calcium Phosphate Granules are equivalent to other bone void fillers. Specifically, the geometry, material, and resorption rate/method are similar to the following devices:

1. Pro Osteon® 500R- Resorbable Bone Void Filler by Interpore International (K980817).
2. Osteoset™ Bone Void Filler by Wright Medical (K960978 and K963562).

Laboratory and Animal Testing was also used to show substantial equivalence.

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biomet@biomet.com



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dalene T. Binkley
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K011531

Trade/Device Name: Calcium Phosphate Granular Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: June 18, 2002
Received: June 20, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

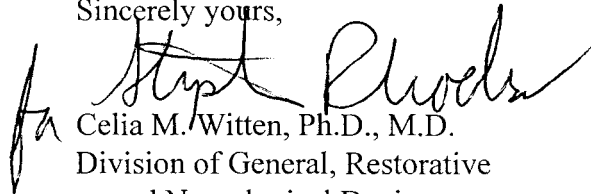
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K011531

DEVICE NAME: Calcium Phosphate Granules

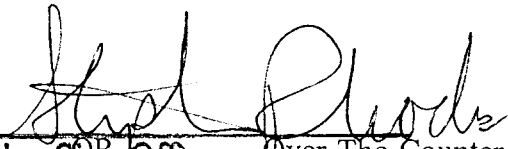
INDICATIONS FOR USE:

Calcium Phosphate Granular Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The granules are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use x
(Per 21 CFR 801.109)


(Division Sign-Off) Over-The-Counter-Use
Division of General, Restorative (Optional Format 1-2-96)
and Neurological Devices

510(k) Number K011531

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